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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,429	02/01/2007	Richard A. Bond	8077-005-US	9681

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EXAMINER

SIMMONS, CHRIS E

ART UNIT	PAPER NUMBER
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1612

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02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,429	Applicant(s) BOND, RICHARD A.	
	Examiner Chris E. Simmons	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-14, 19, 20, 37-42, 48, 49, 52, 55 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 7-14, 19, 20, 37-42, 48, 49, 52, 55 and 60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 7-14, 19-20, and 37-41, drawn to a method for treating a disease or condition comprising administering an inverse agonist for the G protein coupled receptors (GPCR) that causes an increase in the population of GPCRs. Please see species election outlined below.

Group II, claim(s) 42, 48, and 49 drawn to a method of screening comprising the steps of providing a population of specific GPCR, contacting the cells with compound, and determining the constitutive basal level of activity of the GPCRs in the absence and presence of the compound. Please see species election outlined below.

Group III, claim(s) 52, drawn to a method for screening comprising providing cells containing a population of specific GPCR, contacting the cells with compound, and determining the receptor population or receptor density of the GPCRs in the cell in the absence of the compound and in the presence of the compound. Please see species election outlined below.

Group IV, claim(s) 55, drawn to a method for treating a disease or condition associated with the activity of GPCR comprising administering an inverse agonist for the GPCR that prevents the decrease in the population of GPCRs. Please see species election outlined below.

Group V, claim(s) 60, drawn to a composition. Please see species election outlined below.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature (i.e., a composition comprising an inverse GPCR agonist) is taught in the prior art; therefore, the common technical feature is not a special technical feature, *a posteriori*, when the teachings in USP 4,402,976 are considered. The '976 patent teaches a composition comprising nadolol (title).

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In order to be fully responsive to this election requirement, Applicant must further elect:

If Group I is elected:

1. a single disclosed disease or condition for the specification or the claims (e.g., congestive heart failure, etc. – in claim 37)
2. a single disclosed inverse agonist for the GPCR (e.g., nadolol, carazolol, etc. – in claim 10)

3. whether an additional agent is present; if so, Applicant must further elect a single disclosed additional agent (e.g., albuterol, bitolterol, clenbuterol, clorprenaline, salbutamol, etc. – in specification, ¶¶ 162 and 170)
4. a single disclosed GPCR (e.g., β_3 -adrenergic receptors, dopamine, etc – in claim 40)
5. whether the composition further comprises an agonist to the GPCR; if an additional agonist is present.

If Group II or Group III is elected:

1. a single disclosed inverse agonist for the GPCR (e.g., nadolol, carazolol, etc. – in specification, ¶ 0021)
2. a single disclosed GPCR (e.g., β_3 -adrenergic receptors, dopamine, etc – in specification, ¶ 0024).

If Group IV is elected:

1. a single disclosed disease or condition for the specification or the claims (e.g., congestive heart failure, obesity, etc. – in specification, ¶ 0007)
2. a single disclosed inverse agonist for the GPCR (e.g., nadolol, carazolol, etc. – in specification, ¶ 0021)
3. a single disclosed GPCR (e.g., β_3 -adrenergic receptors, dopamine, etc – in specification, ¶ 0024).

If Group V is elected:

1. a single disclosed inverse agonist for the GPCR (e.g., nadolol, carazolol, etc. – in specification, ¶ 0021)

2. a single disclosed second agent (e.g, albuterol, bitolterol, clenbuterol, clorprenaline, salbutamol, etc. – in specification, ¶¶ 162 and 170)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 42, 52, 55, and 60.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the common technical feature (i.e., a composition comprising an inverse GPCR agonist) is taught in the prior art; therefore, the common technical feature is not a special technical feature, *a posteriori*, when the teachings in USP 4,402,976 are considered. The '976 patent teaches a composition comprising nadolol (title).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571)

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272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chris Simmons
Patent Examiner
AU 1612

February 04, 2008

Frederick Krass
Supervisory Patent Examiner
AU 1612

